

APPEAL
Serial No.: 09/418,536
Docket# A24,285

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Before the Board of Patent Appeals and Interferences

In re the Application of

Inventors : Daniel J. Powers et al.
Application No. : 09/418,536
Filed : October 14, 1999
**For : METHOD AND APPARATUS FOR PROVIDING
ON-SCREEN INCIDENT REVIEW IN AN AED**

APPEAL BRIEF

On Appeal from Group Art Unit 3762

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I. REAL PARTY IN INTEREST

The real party in interest is the assignee of the present application, Koninklike Philips Electronics, Eindhoven, Netherlands.

II. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences.

III. STATUS OF CLAIMS

Claims 1-16 and 18-28 stand finally rejected and form the subject matter of the present appeal.

IV. STATUS OF AMENDMENTS

No amendments were submitted in response to the Final Rejection mailed September 17, 2003. A Request for Reconsideration After Final Rejection submitted on October 20, 2003 was entered.

V. SUMMARY OF THE INVENTION

As described on page 1 of the specification, automatic external defibrillators (AEDs) are increasingly being located in public places such as airports, offices, and public facilities so that they are immediately available in the event someone suffers sudden ventricular fibrillation. These automated units are designed to enable any layperson to administer a life-saving shock to the patient. At a later time a trained medical professional may arrive or the patient transported to a hospital where the medical professional will generally want to review the treatment administered and the

patient's ECG at the time of the shock. As mentioned on page 2, AEDs conventionally do not have on-board printers which would print out this recorded data. Paper-based ECG printers are generally found only on large, multi-feature defibrillators. The present invention solves this limitation by enabling the AED operator to review previously-recorded ECG data stored on the unit while the unit continues to monitor the patient. As shown in Figs. 1, user input 28 to memory 22 in an AED enables ECG data stored on the AED to be displayed on the unit's visual image generator 24 during an "incident review mode." of operation. As explained on page 7, lines 11-29, as the stored data is reviewed during this mode the AED can continue to monitor the patient's current ECG waveform so that a further shock can be administered if needed. A shock incident is carried out as described on page 10, lines 12-18 after monitoring and analysis of the patient's current ECG data and the incident information including patient ECG information is stored on a data card 117 as describe on page 10, lines 19-22. Fig. 3 shows an AED 100 in which this recorded incident information is replayed in annotated form showing the time of the shock on the LCD screen 118 of the AED. In the circumstance in which the AED is continuing to monitor the patient's ECG, both the historical ECG data along with the currently monitored ECG data can be displayed as described on page 13, lines 1-12. The two data sets may be distinguished by a legend or color coding of the ECD data as described on page 13. A flowchart showing the steps of monitoring while conducting an incident review is shown in Fig. 4. The recorded ECG data is displayable offline by using the incident review mode after the monitoring and therapy function of the defibrillator has been discontinued, as described on page 11, lines 15-26.

VI. ISSUES

1. Whether Claims 1-12, 14 and 18-28 stand correctly rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Skelton et al. (U.S. 6,292,692) in view of Rockwell et al. (US 6,141,584).

2. Whether Claims 13 and 15-16 stand correctly rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Skelton et al. (U.S. 6,292,692) in view of Rockwell et al. (US 6,141,584) and further in view of Powers et al. (US 5,879,374).

VII. GROUPING OF CLAIMS

Claims 1-16 and 18, comprising an independent method claim and its dependent claims, are drawn to a method of reviewing incident data on an external defibrillator and stand or fall together. Claims 19-28, comprising an independent apparatus claim and its dependent claims, are drawn to an external defibrillator and stand or fall together. It is respectfully submitted that these two groupings should be separately considered, as the method of the first group can be practiced on apparatus other than that of the second group.

VIII. ARGUMENT

The claims at issue are drawn to automated external defibrillators (AEDs). At the time of a heart attack trained medical professionals may not be at hand. Recognizing this, AEDs are designed to be operated by a layperson to resuscitate a

patient. The AED does this after a automatic analysis of the patient's cardiac ECG signal and makes a determination that a resuscitating shock is called for. The data, events and timing of such an incident are, in accordance with the present invention, stored by the AED. When a medical professional arrives or the patient is taken to a hospital, a trained medical professional will often want to review this stored data. An embodiment of the present invention will enable the medical professional to review the stored incident data on the screen of the AED while the AED continues to monitor the patient's ECG so as to detect the possible need for a further defibrillating shock. The medical professional can even review the stored incident data while watching the current ECG waveform on the screen. Thus the best possible medical care may be rendered in the most timely manner.

As the Board will quickly recognize, Skelton et al. is the principal reference in this case as the Examiner is relying on Skelton et al. to provide teachings of important aspects of the present invention. As the Board will also quickly see, the features and functions which the Examiner is trying to impute to certain vague generalities of Skelton et al. are simply not there. For example, key passages upon which the Examiner relies are in column 6 and column 12 of Skelton et al. The Examiner says that these passages show:

“The ECG waveform displayed on the screen is controlled as shown in figure 10 using the buttons (70) associated with the “Trace Menu” window (162). The waveform could be the current waveform or a historical waveform (col. 6 @ 15-25; col. 12 @ 13-22)...Recorded data is made available for review (col. 6 @ 15-25)/ accumulated ECG data can be reviewed (col. 12 @ 13-16), hence enabling the user to review any of the historical data accumulated by the device. Based on operator selection, up to three waveforms can be displayed on the screen (figure 4 (98 a-c); col. 12 @ 10-29), hence the two waveforms displayed simultaneously on the screen are read as the previously recorded ECG data and the currently monitored ECG data.”

Now the cited passages are closely examined. The Skelton et al. device is a multi-functional machine with different modules that perform a plurality of different medical treatments, including a defibrillation module 12, cardiac pacing (col. 7), blood pressure medical treatment module (col. 8), pulse oximeter medical treatment module (col. 8), and a respiration monitor (col. 11). FIG. 4 does show a display which can show up to three graphical traces, as the Examiner contends. The "Trace Menu" buttons 70 allow the wave forms to be toggled on and off (col. 12, lines 22-26). But the wave forms 98a-98c are the outputs of the various medical treatment device modules, as stated at col. 9, lines 64-67. One could be an ECG trace, another could be blood oxygen level, and a third could be the patient's respiration cycle, for instance. The traces are not the current ECG waveform and a historical ECG waveform as the Examiner contends.

Historical data, that is, recorded physiological data or user inputs, are recorded by the use of log functions and devices on the Skelton et al. device, as stated at col. 6, lines 18-27 and lines 59-63. The Skelton et al. device displays this data by means of its chart or strip printer 62 (col. 9, lines 31-37). The logged data can be printed out by the strip printer module so that a service provider can see what medical interventions were performed, including the type and time of treatment entered with buttons 68 from screen portion 122 in FIG. 6. See col. 10, line 53 to col. 11, line 27. The Skelton et al. device is no different from the prior art system referred to on page 2 of the present specification, by which the historical treatment data is reviewed only by a strip chart print-out. There is no display of historical data on the screen of the Skelton et al. device as the Examiner contends.

It is seen that the defibrillation function of the Skelton et al. device is performed in the normal manner. An “ECG analysis medical treatment module” monitors the patient’s ECG waveform and, if ventricular fibrillation is detected, this module sends a signal to the “defibrillator medical treatment module”, which then fires a defibrillation pulse. See col. 5, lines 26-65. If a subsequent medical professional wants to review a prior treatment, the treatment log is printed out and reviewed as discussed at the top of column 11.

The Examiner points to lines 15-16 in col. 12 (“three graphical traces may be generated from accumulated data and displayed to a user”) to support the contention that the Skelton et al. device displays both the current ECG trace being monitored by the defibrillator module and a historical ECG trace. But a reading of the patent, particularly at the bottom of column 9, makes clear that “accumulated data” is that which has been currently acquired from the sensors of the different treatment modules, such as ECG, blood oxygen, blood pressure, and respiration data. When Skelton et al. discuss recorded data they refer to “logged” data, as shown at the bottom of column 10. It will further be noted that this phrase in col. 12 is in the discussion of the respiration monitor, not in the discussion of the defibrillation or ECG analysis modules. It is clear that the cited phrase is not a teaching to display both the current ECG data being monitored by the defibrillator and historical ECG data simultaneously.

(1) Claims 1-12, 14 and 18-28 were rejected under 35 U.S.C. §103(a) as being unpatentable over US 6,292,692 (Skelton et al.) in view of US 6,141,584 (Rockwell et al.) Claim 1 calls for a method of reviewing incident data on an external defibrillator having a screen, including activating an incident review mode in which

the previously recorded ECG data stored in memory and the currently monitored information are displayable simultaneously on the defibrillator screen of the defibrillator while the patient is being monitored by the defibrillator. As explained above, there is no suggestion in Skelton et al. of the ability to simultaneously display previously recorded and currently monitored ECG data on a screen of the Skelton et al. device. There is also no ability in Skelton et al. of the ability to display previously recorded ECG data on the device screen while the patient continues to be monitored for defibrillation. Rockwell et al., which was cited for its disclosure of a defibrillator and communication system by which an event summary can be generated automatically at handoff, does not show or suggest this teaching which is missing from Skelton et al. Accordingly it is respectfully submitted that Claim 1 and its dependent Claims 2-16 and 18 are patentable over Skelton et al. and Rockwell et al.

Claim 19 describes an external defibrillator with a screen and an incident review output comprising a visual image generator, wherein the incident review output retrieves the incident data from memory upon activation of the incident review activator by the user and simultaneously displays the retrieved incident data on the defibrillator screen and the current patient monitoring while the patient is being monitored by the defibrillator. As explained above, neither Skelton et al. nor Rockwell et al. show or suggest the simultaneous display of retrieved incident data on the defibrillator screen and the current patient monitoring while the patient is being monitored. Accordingly it is respectfully submitted that Claim 19 and its dependent Claims 20-28 are patentable over Skelton et al. and Rockwell et al.

(2) Claims 13 and 15-16 were rejected under 35 U.S.C. §103(a) as being unpatentable over US 6,292,692 (Skelton et al.) in view of US 6,141,584 (Rockwell

et al.) and further in view of US 5,879,374 (Powers et al.) Powers et al. was added to Skelton and et al. and Rockwell et al. for its teachings of an external defibrillator with automatic self-testing, the triggering of self-testing by battery insertion, and the use of a gate array for a low power system monitor. However, Powers et al. does not show or suggest the ability to simultaneously display previously recorded and currently monitored ECG data on a screen of an external defibrillator, a feature of Claim 1 which Skelton et al. and Rockwell et al. also fail to provide. Accordingly it is respectfully submitted that Claim 1 and its dependent Claims 13 and 15-16 are patentable over the combination of Skelton et al., Rockwell et al., and Powers et al.

The "Request for Reconsideration After Final Rejection" provides a good summary of the issues in this appeal and their proper disposition.

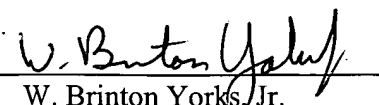
Accordingly, it is respectfully requested that this Honorable Board reverse these grounds of rejection under 35 U.S.C. §103(a).

IX. CONCLUSION

Based on the law and the facts, it is respectfully submitted that none of the appealed claims are obvious in view of the applied references. Accordingly, it is respectfully requested that this Honorable Board reverse all grounds of rejection stated in the Final Rejection.

Respectfully submitted,

DANIEL J. POWERS ET AL.

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X. APPENDIX: THE CLAIMS ON APPEAL

1. (Previously presented) A method of reviewing incident data on an external defibrillator having a screen, comprising:

deploying the defibrillator for use in an emergency, wherein the defibrillator is attached to a patient;

monitoring ECG data from the patient;

recording the monitored ECG data in memory; and

activating an incident review mode in which the previously recorded ECG data stored in memory and the currently monitored information are displayable simultaneously on the defibrillator screen of the defibrillator while the patient is being monitored by the defibrillator without the need to attach the defibrillator to another external device for display, and said recorded ECG data also being displayable offline.

2. (Original) The method of claim 1 further comprising:

retrieving the recorded ECG data from memory; and

replaying the recorded ECG memory on a visual image generator.

3. (Original) The method of claim 1 wherein the activating step is accomplished by user intervention.

4. (Original) The method of claim 2 wherein the replaying step occurs automatically without user actuation of an activation button.

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5. (Original) The method of claim 1 wherein the recording step includes recording audible data received from a microphone into memory.

6. (Previously presented) The method of claim 2 wherein the replaying step further comprises replaying audible data recorded into memory during the recording step.

7. (Previously presented) The method of claim 2 wherein prior to the replaying step, a user select which information is replayed.

8. (Previously presented) The method of claim 7 wherein the user selects from the group consisting of: ECG data, audible data, and a combination of ECG and audible data.

9. (Previously presented) The method according to claim 1 wherein the ECG data is selected from the group consisting of: patient ECG data and patient data therapy.

10. (Previously presented) The method of claim 2 wherein the replaying step is activated by the user depressing soft keys.

11. (Previously presented) The method of claim 2 wherein the replaying step is activated by the user depressing a combination of soft keys.

12. (Original) The method of claim 1 wherein the incident review mode is activated in response to disconnecting the patient from the defibrillator.

13. (Original) The method of claim 1 wherein the incident review mode is activated in response to insertion of a battery.

14. (Original) The method of claim 1 further comprising the step of displaying a legend on a visual image generator that the defibrillator is event review mode.

15. (Previously presented) The method of claim 2 wherein the replaying is optional and the replaying option is presented to a user when the defibrillator is turned off.

16. (Previously presented) The method of claim 2 wherein the replaying is optional and the replaying option is presented to the user when a battery is inserted into the defibrillator.

17. (Canceled).

18. (Original) The method of claim 17 wherein the replaying step further comprises displaying currently monitored ECG data along with the recorded ECG data retrieved from memory.

19. (Previously presented) An external defibrillator comprising:
a controller;
an energy delivery system operable by the controller to deliver an electrical shock from an energy source to an electrode interface;
memory for recording incident data;
a screen;
an incident review activator; and
an incident review output comprising a visual image generator, wherein the incident review output retrieves the incident data from memory upon activation of the

incident review activator by the user and simultaneously displays the retrieved incident data on the defibrillator screen and the current patient monitoring while the patient is being monitored by the defibrillator without requiring communication with an external device.

20. (Original) The external defibrillator of claim 19 wherein the incident review output also comprises an audible sound generator.

21. (Original) The external defibrillator of claim 20 wherein the memory is selected from the group consisting of: flash, EEPROM, ROM and RAM.

22. (Original) The external defibrillator of claim 20 wherein the incident review output also comprises an audible sound generator.

23. (Original) The external defibrillator of claim 19 wherein the incident review activator is a soft key.

24. (Original) The external defibrillator of claim 19 wherein the incident review activator is a combination of soft keys.

25. (Original) The external defibrillator of claim 19 wherein the defibrillator further comprises incident review navigators.

26. (Original) The external defibrillator of claim 24 wherein the incident review navigators enable a caregiver to advance or replay the incident.

27. (Previously presented) The external defibrillator of claim 26 wherein the incident review navigator is a soft key.

28. (Original) The external defibrillator of claim 26 wherein the incident review navigator is a combination of soft keys.